



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

February 19, 1988

Mr. Ronald Wilson
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

#18
RE: NOVANTRONE
(Mitoxantrone hydrochloride)

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,278,689, issued July 14, 1981, was filed on February 17, 1988 under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156.

Douglas W. Robinson
Primary Examiner
Patent Examining Group 120
U.S. Patent and Trademark Office

Patent Law Department
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